

Clean Version of Replacement Paragraphs for Entry During Prosecution of US Application No. 09/554,793

Page 1, first full paragraph:

### BACKGROUND OF THE INVENTION



The invention concerns a device for withdrawing samples of liquid for analytical elements in which the sample is transported in the analytical element in a capillary-active channel from a sample application opening to the determination site for the sample and in which the capillary-active channel is essentially formed by a carrier, a cover and optionally an intermediate layer lying between the cover and carrier. In addition the invention concerns a process for withdrawing a liquid sample into an analytical element with the aid of the said device.

# Page 1, third paragraph:



Test elements or test carrier are often in the form of test strips which are essentially composed of an elongated carrier layer made of plastic material and detection layers which are applied thereto as test fields. However, test carriers are also know which are in the shape of small quadratic or rectangular plates.

# Page 3, first paragraph:

Whereas in the described capillary gap test elements the sample is applied through an opening in the test element which is perpendicular to the capillary gap, in other designs the sample liquid is applied directly into the capillary gap parallel to the direction of spread. This is most simply accomplished by the test element having an edge where the capillary gap ends and which is directly contacted with a sample liquid. When contacted TO TOO with the edge, the sample liquid is taken up by the channel which is capable of capillary liquid transport.





## Page 3, second paragraph:

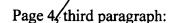
A frequent problem with the latter test elements is that liquid drops which are applied to the sample application opening of the capillary gap are not able to penetrate into the gap. This phenomenon can have different causes. It is conceivable that in the manufacture of such test elements the opening for fabrication reasons does not have the dimensions that are required for a sample drop to enter into the capillary channel for example because the opening has been contaminated or squashed when the test element was cut to length or stamped out. Another reason may be that the hydrophobicity of the materials which are often used to manufacture the said test elements such as for example hydrophobic plastics, impair, delay or prevent penetration of the sample into the capillary gap. For example a liquid drop already does not enter into the inside of a capillary channel or only very slowly if its inner surfaces are indeed hydrophilic but the cut edge is hydrophobic due to the materials used.



## Page 4, second paragraph:

#### **BRIEF SUMMARY OF THE INVENTION**

The invention concerns a device for withdrawing liquid samples for analytical elements in which the sample is transported in a capillary-active channel from the sample application opening to the site of determination of the sample in the analytical element. The capillary-active channel is essentially formed by a carrier, a cover and optionally an intermediate layer lying between the cover and carrier. A notch is formed in one of the surfaces forming the channel capable of capillary liquid transport at the edge of the analytical element that forms the sample application opening. One side of the edge of the sample application opening is at least partially interrupted and the surface opposite to the notch is exposed.



The device according to the invention particularly preferably contains on such notch. However, other designs can also be realized in which several and at least two notches are present together in one surface or are offset on opposite surfaces. There are no limits to





the shape of the notches provided at least part of the edge which forms the sample application opening is at least partially interrupted by the notch. Hence triangular or polygonal as well as round or elliptical forms are possible. Irregular shapes are also not excluded.

## Page 5, second paragraph:

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In this connection hydrophilic surfaces are water-attracting surfaces. Aqueous samples, also including blood, spread well on such surfaces. Such surfaces are characterized among others in that a water drop placed on it forms an acute rim angle or contact angle at the interface. In contrast an obtuse rim angle is formed at the interface between the water drop and the surface on hydrophobic surfaces.

### Page 6, first paragraph:

a measure of the hydrophilicity of a surface. Water for example has a surface tension of 72 mN/m. If the value of the surface tension of the observed surface is much below this value i.e. more than 20mN/m below the surface tension of water, then the wetting is poor and the resulting rim angle is obtuse. Such a surface is referred to as hydrophobic. If the surface tension approximates the value which is found for water then the wetting is good and the rim angle is acute. If, in contrast, the surface tension is the same as or higher than that of the value found for water, then the drop runs and there is a total spreading of the liquid. It is then no longer possible to measure a rim angle. Surfaces which form an acute rim angel with water drops or on which a total spreading of a water drop is observed are referred to as hydrophilic.

# Page 9, first paragraph:



These layers are either applied directly to the desired components of the test element for example by vacuum coating the work pieces with metallic aluminum and subsequently oxidizing the metal, or by using metal foils or metal-coated plastics for the construction of the test carriers which also have to be oxidized to achieve the desired hydrophilicity. In this case metal layer thicknesses of 1 to 500 nm are adequate. The metal layer is subsequently oxidized in which case above all oxidation in the presence of water vapour

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or by boiling in water have proved to be especially suitable methods in addition to electrochemical, anodic oxidation. The oxide layers formed in this manner are between 0.1 and 500 nm, preferably between 10 and 100 nm thick depending on the method. Larger layer thicknesses of the metal layer as well as of the oxide layer can in principle be realized in practice but do not exhibit any additional advantageous effects.

### Page 9, second paragraph:

A second subject matter of the invention concerns a process for withdrawing a liquid sample, in particular a body fluid such as blood, plasma, serum, urine, saliva, sweat etc. with the aid of a device according to the invention. In this process the liquid sample is contacted with the device at the edge of the sample application opening which is interrupted by the notch. The sample liquid is transported into the inside of the device by capillary forces in the channel that is capable of capillary liquid transport so that it can reach its site of determination.



## Page 9, third paragraph:

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#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention is elucidated in more detail by figures 1-6 and by the following examples.

# Page 10, third paragraph, line 10:

Figure 3 shows a plan view of a device in accordance with the present invention.

Figure 4 shows an enlarged perspective view of the device of Figure 3.

Figure 5 shows a plan view of a device in accordance with the present invention.

Figure 6 shows an enlarged perspective view of device of Figure 5.

#### DETAILED DESCRIPTION OF THE DRAWINGS

The numbers in the Figures denote:

Page 11, second paragraph:

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The capillary zone (3) extends from the sample application opening (4) to the opposite end of the detection element (2) and thus ensures that the sample liquid can contact the whole area of the detection element (2). The capillary zone (3) further ensures that a homogeneous sample distribution over the detection element (2). The sample application opening (4) and vent opening (6) limit the capillary active region (3) in the direction of capillary transport.

## Page 12, second paragraph:

A detailed enlargement of a perspective view of the sample application area of a particularly preferred embodiment of the test element according to the invention is shown in Figure 2. The notch (5) in the carrier (1) facilitates penetration of a sample liquid from the sample application opening (4) into the capillary active zone (3) which in the present case is formed by the carrier (1), intermediate layer (9) and cover (7). In addition to the shape shown the notch can also have any other desired shape which serves the purpose according to the invention. Among others semicircular, triangular

## Page 13 first paragraph:



or polygonal shapes and the use of one or several adjacent staggered opposing notches are possible. See, for example Figs. 4-6.